HOUSE BILL No. 1065

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-26; IC 25-22.5-1-2.1.

Synopsis: Use of investigational drugs, biological products, and devices. Provides that a manufacturer of an investigational drug, biological product, or device may make the drug, biological product, or device available to a patient who meets certain requirements. Adds to the requirements concerning experimental or nonconventional medical treatment the authority to allow a patient to receive an experimental or nonconventional medical treatment if a physician determines that the patient: (1) has been diagnosed with a terminal disease or condition; and (2) does not have comparable or satisfactory treatment options. Makes a technical correction.

Effective: July 1, 2015.

Culver

January 6, 2015, read first time and referred to Committee on Public Health.

Introduced

First Regular Session of the 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

HOUSE BILL No. 1065

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-193.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 193.5. "Investigational drug, biological product, or device", for purposes of IC 16-42-26, has the meaning set forth in IC 16-42-26-2.**

SECTION 2. IC 16-18-2-302 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 302. **(a)** "Qualified patient", for purposes of IC 16-36-4, has the meaning set forth in IC 16-36-4-4.

(b) "Qualified patient", for purposes of IC 16-42-26, has the meaning set forth in IC 16-42-26-3.

SECTION 3. IC 16-42-26 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 26. Drugs: Investigational Drug, Biological Product, or

Device

Sec. 1. (a) This chapter does not affect IC 5-10-8-15, IC 12-15-5-9.2, IC 27-8-25, or IC 27-13-7-20.2.

(b) This chapter does not require a manufacturer to make available any investigational drug, biological product, or device.

Sec. 2. As used in this chapter, "investigational drug, biological product, or device" means an investigational or experimental:

(1) drug;

(2) biological product; or

(3) medical device;

that has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial, but has not been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial.

Sec. 3. As used in this chapter, "qualified patient" means a patient who meets the requirements under IC 25-22.5-1-2.1(a).

Sec. 4. (a) A manufacturer of an investigational drug, biological product, or device may make available the investigational drug, biological product, or device to a qualified patient.

(b) A manufacturer may do any of the following:

(1) Provide an investigational drug, biological product, or device to a qualified patient without receiving compensation.

(2) Require a qualified patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

Sec. 5. This chapter does not create a cause of action against a manufacturer of an investigational drug, biological product, or device for any harm to a qualified patient resulting from use of an investigational drug, biological product, or device.

SECTION 4. IC 25-22.5-1-2.1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 2.1. (a) An individual who consents under IC 34-18-12 may receive any experimental or nonconventional medical treatment if:

(1) a licensed physician has personally examined the individual and agrees to treat the individual;

(2) **the treating physician determines:**

(A) there is no reasonable basis to conclude that the medical treatment, when administered as directed, poses an unreasonable and significant risk of danger to the individual receiving the medical treatment; **or**

(B) the:

(i) individual has been diagnosed with a terminal disease

or condition and does not have comparable or satisfactory treatment options that are approved by the federal Food and Drug Administration and that are available to diagnose, monitor, or treat the individual's disease or condition; and

(ii) probable risk to the individual from the experimental or nonconventional medical treatment is not greater than the probable risk from the individual's disease or condition; and

(3) the **treating** physician has provided the individual with a written statement and an oral explanation of the medical treatment that the individual has acknowledged by the individual's signature or the signature of the individual's legal representative and that discloses the following:

(A) That the medical treatment is experimental or nonconventional.

(B) That the **investigational** drug, **biological product,** or ~~medical~~ device **(as defined in IC 16-42-26-2)** has not been approved by the ~~United States~~ **federal** Food and Drug Administration for any indication.

(C) The material risks generally recognized by a reasonably prudent physician of the medical treatment's side effects.

(b) If the medical treatment is to be provided on an inpatient or outpatient basis at a hospital licensed under IC 16-21, then that type of treatment must have been approved by the governing board of the hospital or by a ~~commitee~~ **committee** of the hospital authorized by the governing board to approve the types of experimental or nonconventional medical treatments that may be provided at the hospital on an inpatient or outpatient basis.

(c) The medical licensing board shall develop protocols for medical treatments that are provided in a setting other than the inpatient or outpatient hospital setting specified in subsection (b). A physician who fails to comply with a protocol developed under this subsection shall be subject to discipline by the medical licensing board.

(d) This section does not require any person or organization to provide an individual with access to a medical treatment not otherwise commercially available to that individual.

(e) This section does not require:

(1) an insurer;

(2) a fraternal benefit society;

(3) a nonprofit corporation;

(4) a health maintenance organization (as defined in

IC 27-13-1-19);

(5) a preferred provider arrangement under IC 27-8-11; or

(6) a limited service health maintenance organization (as defined in IC 27-13-34-4);

to provide coverage or make payment beyond the terms and conditions of the contract for medical treatment authorized under this section.